**PATENT APPLICATION**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Jun MORI et al.

Application No.: 10/579,055

Filed: May 11, 2006

Group Art Unit: 1614

Examiner: James D. Anderson

Docket No.: 128006

For: PERCUTENOUS ABSORPTION TYPE CEREBRAL PROTECTIVE AGENT

## DECLARATION UNDER 37 C.F.R. §1.132

I, Jun MORI, a citizen of Japan, hereby declare and state:

1. I have a bachelor's degree in pharmacy which was conferred upon me by Toyama Medical and Pharmaceutical University in Toyama, Japan, in 1988, and a doctor's degree in pharmacy which was conferred upon me by University of Toyama in Toyama, Japan, in 2006.

2. I have been employed by Lead Chemical Co., Ltd. since 1995 and I have had a total of 15 years of work and research experience in pharmacology and pharmaceutics.

3. I am a named inventor in the above-captioned patent application.

4. I and/or those under my direct supervision and control have conducted the following tests, and/or have acquired knowledge about adhesive preparation through studying the relevant scientific literature, in support of U.S. Patent Application No. 10/579,055:

(1) Preparation of Percutaneous Absorption Preparations

According to the procedure of Example 1 of the specification, a percutaneous absorption preparation to be tested according to the claimed invention was prepared. That is, a percutaneous absorption preparation of the claimed invention was prepared as follows:

Liquid A was adjusted by mixing 5 parts of sodium polyacrylate, 6 parts of starch acrylate, 9 parts of talc and 35 parts of concentrated glycerin. Liquid B was adjusted by dissolving 2.3 parts of tartaric acid in 21.5 parts of water. Liquid C was adjusted by dissolving 3 parts of 3-methyl-1-phenyl-2-pyrazolin-5-one (hereinafter referred at "EDV") in 5 parts of lactic acid, 5 parts of isopropanol, 1 part of isopropyl myristate, 1 part of 1-menthol and 0.4 part of Polysorbate 80. Liquid B and liquid C were added to liquid A. Also, 2.5 parts of polyacrylate copolymer emulsion and 0.2 part of aluminum hydroxide gel suspended in 3.1 parts of water were added and mixed homogeneously to obtain a mixture (Preparation A) for adhesive preparation.

In addition, according to the procedure of Example 6 of Sugita et al. (US Patent No. 6,723,732) in which the preparation of patchs is disclosed, a percutaneous absorption preparation was prepared as follows. That is, to 805 mg of an aqueous base (3% 1-menthol/30% ethanol/67% phosphate buffer, pH 4), 195 mg of EDV (in place of the active ingredient of Suguita et al.) was added. After exposing of ultrasonic waves for 10-15 minutes, the mixture was stirred with Vortex mixture to prepare a suspension. After 5 equivalents of glycerin, 1 equivalent of titanium oxide and 5 equivalents of aqueous solution of polyvinyl alcohol were uniformly mixed, 2 equivalents of the suspension was added thereto to obtain a mixture (Preparation B) for adhesive preparation.

Further, a mixture (Preparation C) for adhesive preparation was obtained according to the procedure for obtaining Preparation B except that EDV was not added.

(2) Formability, Adhesiveness and Skin Transmission Property

Preparation A was spread on a polyester non-woven fabric, and then covered with a polyethylene film. This was then cut into predetermined dimensions to obtain an adhesive preparation. This adhesive preparation was easily prepared, and adhesiveness between

Preparation A and the non-woven fabric (a support) was good. The adhesive preparation was subjected to "in vitro skin transmission test" stated in the specification, and the transmission property ($AUC_{0\text{-}24h}$) was 3494.23 ± 1442.05 ng·h/ml showing that it has a sufficiently high skin transmission property.

On the other hand, Preparations B and C were in the form of liquid having flowability and no viscosity, and thus could not be spread on a polyester non-woven fabric (a support). Therefore, Preparation B and C showed no adhesiveness with the support, and no adhesive preparation could be obtained and "in vitro skin transmission test" could not be carried out.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine and/or imprisonment under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing therefrom.

Date: Jan. 29. 2010. Jun MORI

Jun MORI